510(k) SUMMARY K081291

DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, PA 17405-0872

CONTACT: Helen Lewis

DATE PREPARED: May 5, 2008 MAY 22 2008

TRADE OR PROPRIETARY NAME: Pre-Cemented Orthodontic Bracket System Extension

CLASSIFICATION NAME: Bracket adhesive resin and tooth conditioner

CFR NUMBER: 872.3750

DEVICE CLASS: II

PRODUCT CODE: DYH

PREDICATE DEVICES: Pre-Cemented Orthodontic Bracket System, K061252
In-Ovation™ C, K060837.

DEVICE DESCRIPTION: The Pre-Cemented Orthodontic Bracket System Extension is comprised of pre-cemented ceramic and metal orthodontic brackets, transfer tray, and the adhesives described in K061252. Components of this system are used exactly as described in K061252 (Pre-cemented Orthodontic Bracket System) with the same fundamental technology and for the same intended use. This modification adds a second ceramic orthodontic bracket to the Pre-cemented Orthodontic Bracket System (K060837).

INTENDED USE: The Pre-Cemented Orthodontic Bracket System Extension is intended for use in bonding orthodontic appliances for orthodontic treatment.

TECHNOLOGICAL CHARACTERISTICS: The Pre-Cemented Orthodontic Bracket System Extension represents a modification to K061252.

All of the components found in the Pre-Cemented Orthodontic Bracket System Extension have been used in legally marketed devices and/or were found safe for dental use. The Pre-Cemented Orthodontic Bracket System Extension has been evaluated and passed biocompatibility testing for devices classified as surface-contacting devices with permanent contact. As there are no changes in formulation from the predicate devices (K060837 and K061252), we believe that no additional biocompatibility testing is required.

We believe that the prior use of the components of Pre-Cemented Orthodontic Bracket System Extension in legally marketed devices, the previous biocompatibility data, and the performance data provided support the safety and effectiveness of the Pre-Cemented Orthodontic Bracket System Extension for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2008

Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International, Incorporated
Susquehanna Commerce Center
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17405-0872

Re: K081291
Trade/Device Name: Pre-Cemented Orthodontic Bracket System Extension
Regulation Number: 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Code: DYH, NJM, EJF
Dated: May 5, 2008
Received: May 7, 2008

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081291

Device Name: Pre-Cemented Orthodontic Bracket System Extension

Indications for Use:

The Pre-Cemented Orthodontic Bracket System Extension is indicated for use in bonding orthodontic appliances for orthodontic treatment.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081291